



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0080]

Guidance on Food and Drug Administration Oversight of Positron Emission Tomography Drug Products--Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled “FDA Oversight of PET Drug Products--Questions and Answers.” This guidance provides questions and answers that address nearly all aspects of the FDA approval and surveillance processes, including application submission, review, compliance with good manufacturing practices, inspections, registration and listing, and user fees.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to this guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled “FDA Oversight of PET Drug Products--Questions and Answers.” In 1997, Congress passed the Food and Drug Administration Modernization Act (the Modernization Act) (Public Law 105-115). Section 121 of the Modernization Act directed FDA to establish appropriate approval procedures and current good manufacturing practices (CGMP) for PET drugs. The procedures were finalized and an implementation timeline was instituted on December 10, 2009, when FDA published regulations that described the minimum CGMP standards that each PET drug manufacturer is to follow during the production of a PET drug (see part 212 (21 CFR part 212)).<sup>1</sup> Under the requirements of section 121 of the Modernization Act, within 2 years following that publication date, a new drug application (NDA) or abbreviated new drug application (ANDA) must be submitted for any PET drug marketed for clinical use in the United States.

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<sup>1</sup> The regulation, CGMP guidance, and supportive information, including historical documents, are available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm085783.htm>.

Recognizing that many PET drug producers are unfamiliar with the drug approval process, FDA issued several guidance documents specific to PET drug producers,<sup>2</sup> and held a public meeting in March 2011 to assist applicants in preparing NDAs and ANDAs for the three most commonly used PET drugs. Numerous questions have been raised since that public meeting on all aspects of FDA oversight of PET drugs. This guidance is being issued to respond to the questions that have been submitted to date, and it will be revised periodically to respond to additional questions that have been submitted and are expected to be submitted in the future.

A draft guidance of the same title was announced in the Federal Register on February 27, 2012 (77 FR 11553), and Docket No. FDA 2012-D-0080 was open for public comment until May 29, 2012. We received one set of comments from industry. We have carefully considered the comments, and where appropriate, we have made corrections, added information, or clarified the information in this guidance in response to the comments or on our own initiative. In addition, we have added six new questions and answers (see questions 63, 64, 65, 66, 88, and 89).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the FDA oversight of PET drugs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to

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<sup>2</sup> We update guidances periodically. To make sure you have the most recent version of a guidance, check FDA's

<http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

### III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 314 were approved under OMB control numbers 0910-0001 and 0910-0338; the collections of information in 21 CFR part 312 were approved under OMB control number 0910-0014; the collections of information in part 212 were approved under OMB control number 0910-0667; the collections of information in 21 CFR parts 210 and 211 were approved under 0910-0139; and the collections of information in 21 CFR part 207 were approved under OMB control number 0910-0045. The guidance also refers to collections of information associated with submitting Form FDA 3397 (Prescription Drug User Fee Cover Sheet), approved under OMB control number 0910-0297.

### IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: November 28, 2012

Leslie Kux,

Assistant Commissioner for Policy.

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